Internal Audit Check list

Vandagraph Sensor Technologies Ltd
Technical Files

Created:	17/May 1995	**Audit No 12**	
Revised:	27 March 2025		Page 1 of 6
Audit Date	27/3/25	Auditor Helen Lamb	ISO

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
VST Ltd ISO9001:2015 10.2.1	When a nonconformity occurs, including any arising from complaints, the organization shall: a) react to the nonconformity and, as applicable: 1) take action to control and correct it; 2) deal with the consequences; b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by: 1) reviewing and analysing the nonconformity; 2) determining the causes of the nonconformity; 3) determining if similar nonconformities exist, or could potentially occur; c) implement any action needed; d) review the effectiveness of any corrective action taken; e) update risks and opportunities determined during planning, if necessary; f) make changes to the quality management system, if necessary. Corrective actions shall be appropriate to the effects of the nonconformities encountered.	Procedures customer complaints index Rdes + titles Doc index Renew meetings
VST Ltd ISO9001:2015 6.1.2	The organization shall plan: a) actions to address these risks and opportunities; b) how to: 1) integrate and implement the actions into its quality management system processes (see 4.4); 2) evaluate the effectiveness of these actions. Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services. NOTE 1 Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision. NOTE 2 Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.	Risk assessments Renew of Risk management Renew External parties
VST Ltd ISO9001:2015 7.1.6	**Organizational knowledge** The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This knowledge shall be maintained and be made available to the extent necessary.	Doc index

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	When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates. NOTE 1 Organizational knowledge is knowledge specific to the organization; it is generally gained by experience. It is information that is used and shared to achieve the organization's objectives. NOTE 2 Organizational knowledge can be based on: a) internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services); b) external sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers)	Staff. experiance Feedback PMS
VST Ltd ISO9001:2015 7.5.3.2	For the control of documented information, the organization shall address the following activities, as applicable: a) distribution, access, retrieval and use; b) storage and preservation, including preservation of legibility; c) control of changes (e.g. version control); d) retention and disposition. Documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system shall be identified as appropriate, and be controlled. Documented information retained as evidence of conformity shall be protected from unintended alterations. NOTE Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.	Doc index Reg Reading Tech files operating procedures
VST Ltd ISO9001:2015 8.2.2	**Determining the requirements for products and services** When determining the requirements for the products and services to be offered to customers, the organization shall ensure that: a) the requirements for the products and services are defined, including: 1) any applicable statutory and regulatory requirements; 2) those considered necessary by the organization; b) the organization can meet the claims for the products and services it offers.	Doc index Route map marketing index management Renew.
VST Ltd ISO9001:2015 8.3.2	**Design and development planning** In determining the stages and controls for design and development, the organization shall consider:	

	a) the nature, duration and complexity of the design and development activities; b) the required process stages, including applicable design and development reviews; c) the required design and development verification and validation activities; d) the responsibilities and authorities involved in the design and development process; e) the internal and external resource needs for the design and development of products and services; f) the need to control interfaces between persons involved in the design and development process; g) the need for involvement of customers and users in the design and development process; h) the requirements for subsequent provision of products and services; i) the level of control expected for the design and development process by customers and other relevant interested parties; j) the documented information needed to demonstrate that design and development requirements have been met.	Renew meetings Doc index tech files marketing index
VST Ltd ISO9001:2015 8.3.3	**Design and development inputs** The organization shall determine the requirements essential for the specific types of products and services to be designed and developed. The organization shall consider: a) functional and performance requirements; b) information derived from previous similar design and development activities; c) statutory and regulatory requirements; d) standards or codes of practice that the organization has committed to implement; e) potential consequences of failure due to the nature of the products and services. Inputs shall be adequate for design and development purposes, complete and unambiguous. Conflicting design and development inputs shall be resolved. The organization shall retain documented information on design and development inputs.	management Review Feedback tech files marketing index supplier Renew QA system
VST Ltd ISO9001:2015 8.5.6	**Control of changes** The organization shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with	Doc index

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	requirements. The organization shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.	Tech files Renew meetings
VST Ltd ISO9001:2015 8.7.2	The organization shall retain documented information that: a) describes the nonconformity; b) describes the actions taken; c) describes any concessions obtained; d) identifies the authority deciding the action in respect of the nonconformity.	QA system Doc Index Procedures

Paper files are becoming obsolete as electronic documentation supersedes them.
All CE Technical files should be in Intrastats Document Index.
Emails can be found in Gmail, Goldmine and documentation in Intrastats.

	Question	Comments	Y/N
1	Review Last years Audit. Update processes if required. Are all follow on Issue resolved satisfactory.	Nothing outstanding No Non conformances arising	Y
2	Check the list of current CE Files in Intrastats. Do all our products have a CE File. Review list and see if any are missing. ISO – Tech Files, top dark blue section ad the light blue OBL below.	From last Audit VST Does not have own products: Do have tech files	Y
3	Check Cross reference in Intrastats – Family Types. ISO – Tech Files Are all the Products present review	N/A	
4	Check that all Viamed Products (dark blue at the top) are Green for PMS – Post market surveillance. List those not and Issue to technical manager.	N/A	
5	Check that all Viamed Products and OBL's (dark blue and light blue the top two sections) are blue for Risk assessment. List those not and Issue to technical manager.	N/A	

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6	Do all files contain the Basic information required. Are there any Red areas. Cross reference. ISO – Tech files – second icon Cross ref families and files/regulations – ISO BSI Required – Viamed Products – Submit. Speak to quality controller and ask if there are any problem areas, the system is highly complex and understanding of this is not required by auditor.		N/A
7	Are MDA guidelines are available for classification information. In ISO- Tech Files	This is an Intrastats automatic process when developing a new product.	N/A
8	Check that form RG2 has been completed and submitted to MDA for any Class I products. ISO Tech Files, the bracketed number is the CE classification. This is in the check list for when we develop a new Viamed product.	Check the (1)'s and see if they have the MDA letter present. *RG2 form discontinued. As of 2016 DORS MHRA account required.	N/A
9	Check the Canadian Medical Devices CMDCAS form is filled in annually. ISO – Tech Files (At present the microstims are our only products that we sell to Canada)	We No Longer CMDCAS. Can ignore this question for now	
10	Pick one of our Files in the ISO – Tech Files Dark Blue and answer the following No VST Products.		
11	Have there been any product changes since the last Audit		N/A
12	Have Risk assessments been completed on change		N/A
13	Have there been any classification changes		N/A
14	Any new accessories.		N/A
15	Any label changes		N/A
16	Any User information changes		N/A
17	Any sales leaflet changes		N/A
18	Any Data sheet changes		N/A
19	Any maintenance or service manual changes		N/A
20	Any other major changes effecting CE Files		N/A

Review the below processes tasks and audits and ensure they are completed in a timely manner.

List Processes Per Title

Clone from Docid

ISO Controller					
Process Scope	**Roll Task Roll Audit**	**Risk**	**Action**	*	Notes
PROCESSID **7071** The process by which re view and risk assess all product files, check that no Products / Designs have changed significantly to warrant informing any notified bodies eg. MDD / BSI / CMDCAS or any other related Body.	Task: 50 3542985 Managing Director Audit :14 3278562 Company Secretary	Freq 1 Risk 3 Overall 3	Task 2M Audit 12M		
PROCESSID **7172** Check that no Products / Designs have changed significantly to warrant informing MDD / Bsi / CMDCAS or any other related Body.	Task: 50 3542985 Managing Director Audit :	Freq 1 Risk 1 Overall 1	Task 2M		
Audits					
Process Scope	**Roll Task Roll Audit**	**Risk**	**Action**	*	Notes
PROCESSID **7725** To carry out Audit 12 CE Files Viamed	Task: 359360 Audit :16 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M		
PROCESSID **7773** To carry out Audit 12 CE Files VST	Task: 359361 Audit :176 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M		

Rolling Tasks Linked to Document :Task (16) Task (176) Task (50)